

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N-0202]

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Agency Information Collection Activities; Proposed Collection; Comment Request; Assessment of Public Perceptions and Knowledge of Clinical Trials and Informed Consent Human Subject Protection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on a proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey of U.S. consumers' knowledge and attitudes about clinical research and informed consent in clinical research.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information via the internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be

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identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collections of information set forth in this document.

With respect to each of the following collections of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Assessment of Public Perceptions and Knowledge of Clinical Trials and Informed Consent

FDA regulates clinical research of products subject to section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and title 21 of the Code of Federal Regulations (21 CFR) to ensure that products approved for marketing are safe and effective for use. FDA is also charged with ensuring protection of the rights and welfare of human subjects participating in clinical research. Matters involving human subject protection during clinical drug trials are evaluated within the Division of Scientific Investigations in FDA's Center for Drug Evaluation and Research.

FDA regulations describe the requirements for informed consent of study subjects in clinical research in part 50 (21 CFR part 50). Part 50 requires that, to protect clinical research subjects, subjects must be adequately informed before they consent to participate in clinical research. The informed consent process, which is an essential part of human subject protection in clinical trials, is a process of information exchange: A person who is considering participating in clinical research learns about the research, makes an educated decision about participating, and is provided with additional information on a continuing basis, as needed, so as to remain adequately informed throughout participation in the study.

Examination of the available medical literature provides little information on the extent to which persons who may consider participating in FDA regulated clinical research understand clinical research or the informed consent process. We (FDA) propose to perform a survey, the goal of which is to gain information about the general public's perceptions and knowledge about clinical research and informed consent. To accomplish this goal, a

sample of the general public will be asked to answer a questionnaire in a mall-intercept survey.

Seven hundred and fifty adult males and females (over the age of 18) who come from varied socioeconomic, ethnic, and educational backgrounds will be recruited for participation. A sample of nine subjects will be interviewed in a 30-minute pretest that will be used to help refine the questionnaire as needed, based on feedback from the pretest participants. Thereafter, the remaining subjects will participate in 15-minute interviews conducted at appropriate facilities in three geographically distributed shopping malls in the United States: Northeast, Midwest, and West.

Individuals who appear to be age appropriate will be approached by recruiters in public areas of the shopping malls. The recruiters will be clearly identified with name badges or other identification showing their affiliation with the study contractor. The recruiter will briefly explain the purpose of the study and ask the individuals if they are interested in participating in the interview. Those who agree to participate will be interviewed.

The survey questionnaire that will be used is available for review upon request.

Results of the proposed research will be used to help design a plan to educate U.S. consumers about clinical research, human subject protection, and the role of the informed consent process in clinical trials. It is expected that future consumer education programs will enhance protection for future research subjects by making subjects better informed about the clinical research process, their rights in clinical research, and the importance of the informed consent process to their protection.

FDA estimates the burden of this collection of information as follows:

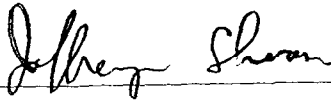
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|-----------------------|-------------------------------|------------------------|--------------------|-------------|
| 9 (pre-test) | 1 | 9 | 0.5 | 4.5 |
| 741 (consumer survey) | 1 | 741 | 0.25 | 185.25 |
| Total | | | | 189.75 |

¹There are no capital costs or operating and maintenance costs associated with this collection of information

Dated: 5-30-03
May 30, 2003.

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Jeffrey Shuren,
Assistant Commissioner for Policy.

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